

**Regulation No. 328/1995, on the advertising of medicinal products,
as subsequently amended by Regulation No. 95/2001**

I. General Provisions

Article 1

Advertising of medicinal products, according to this Regulation, shall include any form of advertising or promotional work in written or oral form, pictorial representations, supply of samples of medicinal products, drug promotional meetings and gatherings, sponsored directly or indirectly by the holder of a marketing authorisation, manufacturer, agent or wholesaler to promote the prescription, sale or use of medicinal products, including natural medicinal products.

Over-the-counter medicinal products may be advertised and promoted among the general public, in Icelandic, in accordance with detailed rules, cf. Chapter II.

Medicinal products, for which a marketing authorisation has been granted in Iceland, may be advertised and promoted, in Icelandic, in journals and newsletters of those health professions, which are qualified to prescribe or distribute medicinal products, i.e. physicians, dentists, pharmacists, pharmacy technicians and registered nurses, as well as veterinarians, and students of these professions, in accordance with detailed rules, cf. Chapter III.

Article 2

The provisions of this Regulation shall not apply to:

- a) markings on the labelling of medicinal products and outer packaging or the accompanying package leaflets;
- b) correspondence, which is necessary to reply to specific questions about a particular medicinal product, nor any accompanying documentation about the medicinal product which is not an advertisement;
- c) announcements and correspondence relating to packaging changes, warnings on side effects, trade catalogues and price lists, provided that they include no product claims.

Article 3

An advertisement for a medicinal product must provide correct and relevant factual information on the medicinal product. Information in advertisements shall always be clear and easily comprehensible and in accordance with the Summary of Product Characteristics (SPC).

An advertisement for medicinal products must encourage rational use of the medicinal products, by presenting them objectively and without exaggerating their characteristics. An advertisement for a medicinal product may not be misleading.

Article 4

Medicinal products may not be advertised on television.

Article 5

The holder of a marketing authorisation, its agent or representative shall keep records of all advertisements and promotions indicating where, when and for whom they were published or held. The records shall be kept for two years and shall be accessible to the State Drug Inspectorate.

The holder of a marketing authorisation, its agent or representative shall preserve scientific documentation on medicinal products which it places on the market and be responsible for providing information on them.

II. Advertising Directed at the General Public

Article 6

[Over-the-counter medicinal products may be advertised and promoted to the general public, cf. however, Article 4.]¹⁾

Advertisements of over-the-counter medicinal products may not mention indications for their use to treat illnesses such as tuberculosis, sexually transmitted diseases, other infectious diseases, cancer and other tumoral diseases, chronic insomnia, diabetes and other metabolic illnesses.

An advertisement for a medicinal product directed at the general public shall be set out in such a manner that it is clear that it is an advertisement and that the product advertised is a medicinal product.

[The Ministry may, after receiving the opinion of the Icelandic Medicines Control Agency and State Epidemiologist, authorise advertisements by medicinal

product producers for vaccination actions which have been approved by the authorities, cf. Article 14.]²⁾

¹⁾Reg. 95/2001, Art. 1.

²⁾Reg. 95/2001, Art. 2.

Article 7

An advertisement for a medicinal product which is directed at the general public shall include at least the following information:

- a) name of the medicinal product, together with the generic name if the product contains only one active constituent;
- b) the names of the active ingredients;
- c) information necessary for the correct use of the medicinal product, including field of usage, important precautions, warnings and dosage;
- d) a clear and easily comprehensible encouragement to read carefully the instructions on the package leaflet or outer packaging of the medicinal product, as applicable.

Article 8

An advertisement for a medicinal product which is directed at the general public may not include anything which:

- a) suggests that a medical consultation or medical treatment/operation is unnecessary;
- b) is an offer of diagnosis and/or purchase of medicinal products by mail;
- c) suggests that the effects of the medicinal product are guaranteed or that it is unaccompanied by side-effects;
- d) states that the effects of taking the medicine are better than, or equivalent to, those of another treatment or medicinal product;
- e) suggests that the health of the person concerned may be enhanced by taking the medicinal product;
- f) suggests that the health of the person concerned may deteriorate if the medicinal product is not taken;
- g) is directed exclusively or in particular at children;
- h) refers to recommendation by scientists, health professionals or individuals who are neither scientists nor health professionals, but who because of their

general acknowledgement or celebrity, could serve as encouragement to others to use medicinal products;

- i) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- j) suggests that the safety or efficacy of the medicinal product is due to the fact that it is a natural substance;
- k) could lead to incorrect self-diagnosis of an illness, because of manner in which it is described or because of a detailed case history;
- l) refers, in improper or misleading terms, to claims of recovery;
- m) uses, in an improper, alarming or misleading manner, pictorial representations of changes in the human body or animals caused by disease or injury, or of the effect of a medicinal product on the human body or parts thereof;
- n) suggests that a marketing authorisation has been granted for the medicinal product.

Article 9

Notwithstanding the provisions of Article 7, the Ministry of Health and Social Security may authorise under special circumstances that an advertisement for a medicinal product which is directed at the general public include only the name of the medicinal product if the objective of the advertisement is solely to draw attention to the name.

Article 10

Medicinal products which are only available upon prescription or medicinal products which contain substances classified by international conventions as habit-forming or narcotic substances may not be advertised to the general public.

Article 11

Samples of medicinal products may not be distributed to the general public.

III. Advertising Directed at Health Care Professionals and Veterinarians

Article 12

Medicinal products available only by prescription may be advertised and promoted among physicians, dentists, pharmacists, pharmacy technicians and registered nurses, as well as veterinarians, and students of these professions.

The advertisement shall be presented in such a manner as makes it unlikely to reach the general public.

Article 13

The advertisement shall be detailed and in accordance with the registration provisions of the medicinal product, the regulation on the form of prescriptions and prescribing of medicinal products, their dispensing and labelling, as well as other instructions as applicable.

The advertisement shall include at least information on the following:

- a) name of the medicinal product,
- b) pharmaceutical form,
- c) concentration of the medicinal product,
- d) name of all active ingredients, which are conspicuously indicated in the advertisement;
- e) name of the marketing authorisation holder and the manufacturer, if applicable,
- f) approved indications,
- g) contraindications,
- h) side effects, precautionary measures, interactions,
- i) dosages,
- j) packaging size(s),
- k) how it shall be dispensed (dispensing classification),
- l) price (approved maximum price),
- m) participation of health insurance in the payment.

Article 14

All advertisements and promotional documents must include, in addition to those items listed in Article 13, the date on which the information was compiled or most recently revised.

An advertisement may refer to scientific research, which has been published in acknowledged journals or books, as supplementary information on registered

properties of a medicinal product. All such references must be accompanied by precise information on the sources, which must be accessible to persons at which the advertisement is directed.

References and data from journals which are not professionally reviewed are not considered as scientific sources, nor are research reports of companies manufacturing or holding a marketing authorisation for the medicinal product.

References, tables and other illustrative matter taken from medical journals or other scientific works which are used in an advertisement must correspond to the original in every detail and precise information on sources must be given.

Article 15

All information contained in the documentation on medicinal products, which are sent for promotional purposes to physicians, dentists, pharmacists, pharmacy technicians and registered nurses, as well as veterinarians, and students of these professions, must be accurate and reflect the state of the art. The information must be verifiable and sufficiently detailed to enable the recipient to form his/her own opinion of the therapeutic value of the medicinal product concerned.

Article 16

Physicians, dentists, pharmacists, pharmacy technicians and registered nurses, as well as veterinarians, and students of these professions may not be offered gifts, money or benefits except when their intrinsic value is minimal and the offer is connected to medical and medicinal occupations.

Hospitality at sales promotions must always be kept within normal bounds and may not be the primary objective of such a promotion. Hospitality must not be extended to other than those professions listed in the first paragraph.

Article 17

Persons authorised to prescribe or dispense medicinal products may not request or accept contributions which are prohibited according to the first paragraph of Article 16, or which are contrary to the second paragraph of Article 16.

IV. Supplying Samples of Medicinal Products

Article 18

Free samples of medicinal products may only be given in person to a physician, dentist or veterinarian, and must be newly registered medicinal products, which are being promoted and are not considered habit-forming or narcotic drugs. The afore-mentioned parties may only be provided with samples of such medicinal products as each of them is authorised to prescribe.

Furthermore, the following conditions shall apply to supplying samples of medicinal products:

- a) samples of medicinal products may only be provided in response to a written request, dated and signed by the physician, dentist or veterinarian in question;
- b) only one sample of a newly registered medicinal product may be provided per year. If the medicinal product is registered in different pharmaceutical forms and/or concentration, one sample of each pharmaceutical form or concentration may be provided;
- c) samples of medicinal products shall be the smallest registered package size of the medicinal product;
- d) samples of medicinal products shall be labelled: "Free medical sample - not for sale";
- e) a sample of a medicinal product must be accompanied by a copy of its registration conditions (e.g. the relevant text in the Icelandic Register of Proprietary Medicinal Products (*Sérlyfjaskrá*);
- f) samples of unregistered medicinal products may not be supplied;
- g) samples of medicinal products containing substances which according to international conventions are classified as habit-forming or narcotic substances may not be supplied.

Article 19

Pharmaceutical companies must keep records of the distribution of samples of medicinal products. The records must be kept for at least two years and supplied to the State Drug Inspectorate for inspection upon request.

V. Sales Representatives for Medicinal Products

Article 20

Medicinal product sales representatives must receive appropriate training from the holder of the marketing authorisation, for whom they work, its agent or representative and have adequate professional knowledge to be able to provide the most comprehensive information possible on the medicinal product which they are promoting.

Article 21

Upon each visit by a sales representative for medicinal products to a party authorised to prescribe or supply medicinal products, the former must provide written information on the registration conditions for the medicinal product they are promoting, including information on the product characteristics, maximum authorised price and the participation of the health insurance in payment for the medicinal product.

VI. Surveillance and penalties

Article 22

The State Drug Inspectorate shall supervise advertisements of medicinal products, pursuant to Article 18 of the Medicinal Products Act No. 93/1994.

The State Drug Inspectorate may prohibit the publication of specific advertisements which violate the provisions of this Regulation. It can also demand that an advertiser publish corrections or supplementary explanations in the same manner as the previous advertisement.

The State Drug Inspectorate shall seek the opinion of the State Committee on Pharmaceuticals in the above-mentioned instances.

If the State Drug Inspectorate sees reason to question the validity of an advertisement of a medicinal product in other respects, for instance for giving false, incomplete or misleading information, the State Drug Inspectorate shall forward it to the Competition and Fair Trade Authority, for examination, cf. Chapter VI of the Competition Act, No. 8/1993.

Article 23

A marketing authorisation holder, its agent or representative, must appoint one party within the company who is to be responsible for all the information material

used for promoting the medicinal products for which it holds marketing authorisations.

The person concerned must ensure that the provisions of this Regulation are complied with.

Article 24

[Infringements against the provisions of this Regulation are liable to penalties and punishment pursuant to Articles 42 and 43 of the Medicinal Products Act., No. 93/1994, as subsequently amended.]¹⁾

¹⁾Reg. 95/2001, Art. 3.

VII. Legal Basis - Entry into Force

Article 25

Provisions of this Regulation are in accordance with Council Directive 92/28/EEC on the Advertising of Medicinal Products for Human Use and the Council Directive 89/552/EEC on the Co-ordination of Certain Provisions laid down by Law, Regulation or Administrative Action concerning the Pursuit of Television Broadcasting Activities.

This Regulation is set by authority of Article 44 of the Medicinal Products Act, No. 93/1994, and shall enter into force at once.

Ministry of Health and Social Security, 2 June 1995.